

Herbert Zech

## Life Sciences and Intellectual Property: Technology Law Put to the Test

Life sciences have developed into one of the leading areas of technology. Being highly innovative and needing huge capital investments, the life sciences industry is heavily dependent on intellectual property rights. However, the function of intellectual property law has to be seen in connection with other areas of law like regulatory and liability law. The life sciences are a typical area of modern technology, challenging the law not only to foster innovation and facilitate technology transfer but also to insure safety and allocate risks. Interestingly, the traditional distribution of legal functions has become blurred in the area of life sciences: Regulatory law provides an incentive for developmental activities like clinical tests while patent law is increasingly used to discourage unwanted activities.

### 1. Introduction

Life sciences have given rise to some of the most important and innovative sectors of industry. Medicine, pharmaceuticals and agriculture<sup>1</sup> show not only high innovation rates but also demand huge investments. Intellectual property (IP) law therefore plays a major role in these sectors. However, intellectual property law has to be seen in perspective with other areas of law as for instance regulatory and liability law. Being highly innovative, the life sciences sector promises not only huge potential benefits to society but also entails inherent risks. Life sciences challenge the law not only to ensure innovations and distribute their potential benefits but also to cope with these risks. Traditionally, IP law fosters innovation and facilitates technology transfer whereas regulatory law limits the risks of a specific technology and liability law allocates the remaining risks. However, this traditional distribution of functions has become blurred especially in the life sciences sector.

The following analysis tries to show how IP can be seen as a part of technology law and how life sciences are one of the major areas where legal intervention meets new challenges. First, the life sciences area will be described as one of the leading areas of technology. Second, technology law will be defined by its functions. Third, IP law will be shown as an important part of technology law. Fourth,

<sup>1</sup> The agricultural sector comprises seeds and crop protection.

current challenges for IP law and technology law as a whole originating from the life sciences and their rapid progress will be illustrated.

## II. Life Sciences

### 1. Using and Treating Living Organisms

From a practical perspective life sciences can be defined as the science behind medicine, pharmacy and agriculture or their corresponding industries. However, they play a certain role in even more industries like the chemical industry (especially as “grey” biotechnology). On a more theoretical level, life sciences can be defined as the use of living organisms (organisms as tools: biotechnology) and the protection of living organisms (organisms as “patients”: medicine, veterinary medicine and plant protection). The term “sciences” is somehow misleading: Although science is the mere pursuit of knowledge, life sciences are especially about the use of specific knowledge, they are technology.

The success of the term “life sciences” can be explained by the fact that many formerly single disciplines like chemistry, biochemistry, physiology, genetics etc. cannot be separated clearly anymore. Moreover, scientific research in the life sciences-area cannot be done without biotechnological tools. Even the line between pure science and its technological application is no longer clear in the life sciences area. Therefore, the use of the term “Life Sciences” is not only practical but also justified.

### 2. Life Sciences as a Leading Technology

Together with information technology and nanotechnology (material science) life sciences represent one of the technological areas with the highest innovation rate. Unlike some areas of information technology (e.g. software programming) in which innovative efforts can be distributed among a large heterarchical network of contributors (open source software),<sup>2</sup> innovations in the life sciences sector typically require substantial investments. This underlines the importance of a viable life sciences industry.

<sup>2</sup> Metzger, Vom Einzelurheber zu Teams und Netzwerken: Erosion des Schöpferprinzips?, in: Leible/Ohly/Zech (eds.), Wissen – Märkte – Geistiges Eigentum, 2010, 79 seqq.

### III. Technology Law: Fostering and Harnessing Innovations

Since the life sciences industry is heavily dependent on capital intensive innovations, it is not surprising that IP law, especially patent law, plays a major role for this industry. This is not only true for the pharmaceutical sector but also for medicinal products, plant protection and increasingly for seeds where the traditional plant breeders' rights do not suit state-of-the-art trait development. However, the function of IP protection has to be seen in connection with the functions of other areas of law as for instance regulatory law and liability law. All of these functions constitute the legal framework for a specific technology.

#### 1. Technology Law Steers Technology and is Driven by Technology

Technology law can be defined as the law (i. e. all legal rules) regulating (in a broader sense) technology. Therefore, technology law encompasses all legal rules influencing the creation of technology (innovation), its distribution (diffusion), its application (use) or the consequences of its use (opportunities and risks). Although there is some discussion about the term technology itself, nowadays technology can reasonably be understood as the application of science based knowledge.<sup>3</sup> Life sciences with their application in science and industry therefore can be understood as an area of technology.

Technology is highly dynamic, which is one of its most important aspects<sup>4</sup> and especially true for life sciences. Constantly evolving technologies form the basis of Schumpeter's famous business cycles. Areas of technology can be divided into separate technologies, i. e. individual methods using a specific application of certain scientific knowledge to solve a specific problem. This closely resembles patent law's fundamental definition of an invention. Innovations, i. e. the creation of new technologies from ideas to applicable inventions and further on to marketable services and products, can be understood as the smallest single entity of whole areas of technology like gene technology or nanotechnology. The function of legal rules in technology law can be explained as a legal intervention at some point of the innovation cycle.

Technology's dynamic also drives legal innovations. The introduction of a new technology sometimes calls for new legal rules. The examples are manifold

3 Technology can be defined as the application of scientific knowledge for practical purposes, especially in industry, cf. Oxford English Dictionary (OED), Oxford University Press 2014, <http://www.oed.com/view/Entry/198469?redirectedFrom=technology#eid>, visited on the 30<sup>th</sup> of September 2014; *Bunge*, Technology as applied science, *Technology and Culture* 7 (1966), 329. Historically, the link between science and technology has not been established before the 19<sup>th</sup> century.

4 *Murswiek*, Festschrift Kriele, 1997, 651, 652; *Schulze-Fielitz*, in: Schulte / Schröder (eds.), *Handbuch des Technikrechts*, 2. ed. 2011, 455, 463 seq.

like combustion engine driven cars, nuclear technology or gene technology. The mutual influence of law and technology can be described as a “coevolution”.<sup>5</sup>

## 2. Four Major Functions of Technology Law

Technology law fulfils four major functions, which can be illustrated referring to the innovation cycle: New technologies are constantly developed, diffused and applied. Accordingly, the law influences the creation, diffusion and application of new technologies. At each of these stages it strives to enhance public welfare. The resulting four major functions are fostering innovation, enabling technology transfer, controlling inherent risks of technology use and assigning responsibilities for resulting damages.

The first two functions (“columns”) of technology law concern the creation and diffusion of innovations. These two functions may be addressed as “enabling” technology.<sup>6</sup> However, the law may also restrict technology; it is not only about creating and diffusing new technologies but also about using them safely and bearing the consequences of their use.<sup>7</sup>

### 2.1 Fostering Innovation: IP Law

First, the law can intervene with the creation of new technologies, especially provide incentives for new innovations where market failures hinder the innovation process. This is the classical role of IP law and will be described in more detail under IV.1. One of its main characteristics is that it is not specific to a certain technology but open to any technology therefore incentivising even the development of unexpected technologies.

### 2.2 Enabling Technology Transfer: IP, Contract and Competition Law

Second, the law plays a role in technology transfer either forcing parties to transfer technologies or, more important, creating a legal framework for the contractual exchange of new technologies. This is also a domain of IP law which creates markets for technology where the information paradox would otherwise hinder the exchange of information goods.<sup>8</sup> IP law is complemented by contract law

5 Eckardt, Technischer Wandel und Rechtsevolution, 2001, 7 seqq.

6 For the technology enabling and technology restricting functions of law see Vieweg, JuS 1993, 894, 895; *idem*, Festgabe Lukes, 2000, 199, 202; Schulze-Fielitz, in: Schulte/Schröder Schröder (eds.), Handbuch des Technikrechts, 2. ed. 2011, 455, 463.

7 To a certain extent even regulatory law may act as a technology enabler since it provides legal certainty about the legality, the due diligence and the liability risk of using a specific technology, cf. Kloepper, NuR 1997, 417, 417 seq.

8 Arrow, Economic Welfare and the Allocation of Resources for Invention, The Rand Corporation, 1962, 609, 615; Burstein, Exchanging Information Without Intellectual Property, Texas

creating the legal framework for the material transfer of IP, for licenses or even for know-how contracts which do not rely on IP protection but only on the protection of trade secrets. A third important component of legal rules concerning technology transfer is competition law. By acting against restraints on competition it keeps technology markets open.<sup>9</sup>

## 2.3 Controlling Inherent Risks: Regulatory Law

Third, technology law encompasses regulatory law, intervening where a regulatory framework is needed to guarantee that a certain technology or area of technology is only used with an acceptable level of risk. Classical examples are legislations concerning steam power, automobiles, nuclear energy or gene technology. Since these legislations try to hedge a specific risk, they necessarily look backwards and can only regulate specific areas of technology.

Regulatory technology law primarily aims at the safety and security of using technologies. However, especially in the life sciences area it may also define legally binding boundaries of technology use which are ethically motivated. This can be due to the involvement of human beings (e. g. when using embryonic stem cells) or nonhuman beings (e. g. with animal testing).

## 2.4 Assigning Responsibilities: Liability Law

The fourth area of technology law is liability law allocating the remaining legally accepted risks and creating incentives for an optimal risk acceptance. This “column” is closely associated with the third (i. e. regulatory law) which defines the necessary diligence when using a certain technology and in some cases provides for strict liability rules.<sup>10</sup> Therefore, general liability rules have to be taken into account together with more specific ones like product liability or liability rules for

Law Review 91 (2012), 228, 229; *Lemley*, The Myth of the Sole Inventor, Michigan State Law Review, 110 (2012), 710, 748 seq.; *Thambisetty*, Patents as Credence Goods, Oxford Journal of Legal Studies 27 (2007), 707, 707 seq. See under IV.2.

<sup>9</sup> However, in order not to pose an undue burden on technology transfer European competition law provides for specific block exemptions, especially the technology transfer block exemption and the research and development block exemption, Commission Regulation (EU) No 316/2014 of 21 March 2014 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of technology transfer agreements and Commission Regulation (EU) No 1217/2010 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to certain categories of research and development agreements; *Turner*, Intellectual Property and EU Competition Law, 2010, 131 seqq.

<sup>10</sup> There is no general clause for a strict liability in Germany. On a European level, the product liability directive provides for a liability regime which requires product defects instead of negligence but still does not comprise development risks (which were unforeseeable at the time of sale), art. 7 (e) 85/374/EEC: “The producer shall not be liable as a result of this Directive if he proves: [...] (e) that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered [...]”

certain areas of technology. Liability rules generally can be categorized according to the level of negligence they require. One of the main questions concerning strict liability rules is whether a certain rule allocates risks that were unforeseeable according to the state of science and technology at the time of the causal act (development risks) to the infringer, the technology user or the damaged party.<sup>11</sup>

### 3. Life Sciences Law as the Law of Life Sciences Innovations

All four functions of influencing technological innovation and its application can be found in life sciences law. It is not only a kind of “practice group” but a dogmatically consistent area of law concerning the use of living organisms as tools (biotechnology) and their treatment as “patients” (medicine, veterinary medicine and plant protection). Being part of technology law, life sciences law strives to foster innovation, enable technology transfer, control inherent risks and assign responsibilities.<sup>12</sup>

### 4. Research Interest: Interaction of Different Functions, Parallel between Loss and Benefit Allocation (Opportunities and Risks)

Looking at the different areas of technology law from the perspective of innovation has the advantage of highlighting the connection between these areas which traditionally are regarded as separate legal disciplines. Moreover, it allows to draw parallels, for instance, to analyse IP law from a liability lawyer’s point of view. When technology law is about creating, distributing, using and bearing the consequences of innovations, the interaction between IP law, contract law, competition law, regulatory law and liability law becomes automatically the focus of juridical interest.

One of these interfaces deserving a closer look is between IP law, especially patent law, and liability law.<sup>13</sup> Whereas patent law allocates the potential benefits (opportunities) of a new and inventive technology to the inventor or a licensee for a limited amount of time, liability law allocates the risks of its legitimate use – but (as long as there is no general clause for a strict liability) only where special strict liability rules exist. Therefore, arguably the allocation of opportunities and risks inherent to new technologies is asymmetric. This is in contrast to a fundamental rule of justice saying that one who enjoys the fruits of a certain activity shall also be the bearer of its risks. A strict liability rule which is not restricted to a certain technology or activity fulfils this criterion to a larger extent (although it might make legal decisions less predictable).

11 Schrupkowski, Die Haftung für Entwicklungsrisiken in Wissenschaft und Technik, 1995, 4 seqq.; Zech, JZ 2013, 21, 22 seq.

12 Zech, Basler Juristische Mitteilungen 2014, 1, 6 seq.

13 Zech, JZ 2013, 21, 26 seqq.

## IV. The Role of IP Law: Fostering Innovation and Enabling Technology Transfer, Technology Neutrality

IP law dominates the first, and, to a certain extent, the second “column” of technology law. IP protection, especially patents, spurs innovation (first column) and promotes the disclosure of secret inventions (second column). Nowadays, there are many more theories about the function of IP law and especially patent law. They all fit into the two main aspects of technology law, i.e. promoting the creation and the distribution of innovations. One important feature of these legal rules is that they are not specific to a certain technology. This is in contrast to regulatory and (most of) liability law and a necessary consequence of patent law’s *ex ante* perspective. Other than regulatory law and most of liability law, patent law concerns future technology whose benefits and risks are yet unknown (and necessarily so).

### 1. Incentives for Innovation: Inventing and Developing

Traditionally, the most important function of patent law is to enable innovations where markets without legal rules would fail.<sup>14</sup> Inventions are public goods which can be used by an unlimited number of persons at the same time, and whose use, once the invention is disclosed, cannot be prohibited by factual means (non-exclusivity). Legal exclusivity enables amortisation of research and development costs (subject to market success) and therefore encourages the creation of inventions.

However, this classical function of patents has been revised and extended. For instance, the role of patents as an indicator for potential investors (especially when patents are held by start-up companies) is now widely accepted.<sup>15</sup> Patents therefore ensure the funding for highly innovative companies. This also increases the average total number of inventions made during a specific period of time.

Another aspect of enabling innovations which is located at a later stage of the innovation cycle (“downstream”) is the commercialization function.<sup>16</sup> Patents not only spur the creation of new inventions but also the further development of such inventions towards a marketable service or product. Especially in the area

<sup>14</sup> *Hettinger*, *Philosophy & Public Affairs* 18 (1989), 31, 47 seqq.; *Landes/Posner*, *The Economic Structure of Intellectual Property Law*, 13; *Ohly*, in: *Ohly/Klippel* (eds.), *Geistiges Eigentum und Gemeinfreiheit*, 2007, 1, 3; *Bechtold*, *GRUR Int* 2008, 484, 485; *Kerber*, *ZGE/IJP* 5 (2013), 245, 248 seqq.; for life sciences innovations see *Haedicke*, in: *Depenheuer/Peifer* (eds.), *Geistiges Eigentum: Schutzrecht oder Ausbeutungstitel?*, 2008, 111, 112; *Moufang*, *I.c.*, 89, 89 seqq., 109; *Uhrich*, *Stoffschutz*, 2010, 101 seq., 111 seqq.

<sup>15</sup> *Cotter*, *Patent Holdup, Patent Remedies, and Antitrust Responses*, *The Journal of Corporation Law* 34 (2009), 1151, 1154 seqq.; *Graham/Merges/Samuelson/Sichelman*, *Berkeley Tech. L.J.* 24 (2009), 1255, 1297 seqq., 1303 seqq.

<sup>16</sup> *Webster/Jensen*, *Macroeconomic Conditions and Successful Commercialization*, 2009, 4 seqq.

of life sciences it is one of the current matters of dispute at which stage of the innovation cycle patent protection should interfere in order to get the optimum overall efficiency.<sup>17</sup> Patents on ideas are not admissible in order to prevent blocking effects for further inventions (especially in new areas of technology). Even further, it is debated whether optimum protection should be pushed to the developmental stage after the basic invention has been made. This is also important to understand some recent developments which are described under V.

## 2. Enabling (and Encouraging) Technology Transfer

Patent law and other IP rights also enable and encourage the distribution of inventions. Especially patents are designed as an incentive for the disclosure of secret inventions.<sup>18</sup> This is considered the second important traditional function of patents. Moreover, patents and IP rights in general are nowadays seen as an instrument to make information goods tradable.<sup>19</sup> By creating a market for inventions, creative works etc. IP rights enable the allocation of such goods via market forces allowing them to be used by the most efficient users instead of being kept secret.

## 3. Technology-Specific and Technology-Unspecific Rules

While regulatory law and, to a certain extent, liability law are specific to a certain technology, IP law (especially patent law) is not (article 27 (1) TRIPS).<sup>20</sup> The reason for this is that IP law has a proactive perspective, trying to enable innovations that are yet to be made and whose usefulness has yet to be tested. Being open about the area of technology or the possible effect of the technology enables the creation of yet unknown technologies. Promoting a specific technology would discourage innovation in other areas whose benefit potentially will only become clear later. Therefore, it cannot be the task of IP law to reward a specific technology.

<sup>17</sup> The life sciences area shows a huge amount of sequential innovations where patent protection for basic innovations may block follow on innovations, cf. *Scotchmer*, Standing on the Shoulders of Giants: Cumulative Research and Patent Law, *Journal of Economic Perspectives* 5 (1991), 29; *Haedicke*, in: *Depenheuer/Peifer* (eds.), *Geistiges Eigentum: Schutzrecht oder Ausbeutungstitel?*, 2008, 111 (114 seq.); *Moufang*, in: *Depenheuer/Peifer* (eds.), o.c., 89 (108); *Zech*, in: *Hilty/Jaeger/Lamping* (eds.), *Herausforderung Innovation*, 2012, 81, 87 seq.; *Krusemarck*, *Die abhängige Schöpfung im Recht des geistigen Eigentums*, 2013, 125 seq. (132).

<sup>18</sup> *Machlup*, *An Economic Review of the Patent System*, 1958, 1; *Beier*, *GRUR Int* 1970, 1, 4 seq.

<sup>19</sup> *Arora/Fosfuri/Gambardella*, *Markets for Technology*, 2001, 143 seq.; *Merges*, *Berkeley Tech. L. J.* 20 (2005), 1477, 1489 seq.; *Uhrich*, 114.; *Godt*, *Eigentum an Information*, 2007, 449 seq., 554 seq.

<sup>20</sup> See for restrictions in legal practice *Burk/Lemley*, *Is Patent Law Technology Specific?*, *Berkeley Tech. L. J.* 17 (2002), 1157 seq.



## V. Challenges in the Life Sciences Area

Especially in the life sciences area the traditional roles of IP rights and regulatory rules are respectively blurred. Regulatory law (more precisely data and market exclusivity) serves as an incentive for developmental activities whereas patent law is used (or is proposed to be used) as an instrument to hinder “unwanted” technologies and to promote “wanted” technologies.

### 1. Regulatory Law as the New IP?

Especially in the life sciences area the use of specific technologies or the distribution of specific products like gene technology products, pharmaceutical products, medicinal products or seeds is often tightly regulated by legal provisions. Although the main function of such provisions is to control the risks of potentially dangerous technologies, they have assumed a secondary function of preventing potential market failures in the development and the production of such technological products.

#### 1.1 Drugs for Rare Diseases

One major example in the pharmaceutical sector is market exclusivity for orphan drugs.<sup>21</sup> In the European Union pharmaceuticals which are recognised as a treatment for rare diseases (i. e. diseases with an occurrence rate of less than 5/10,000<sup>22</sup>) are given a ten years’ market exclusivity.<sup>23</sup> Although the aim of this provision is clearly to incentivise the development of new orphan drugs by granting market exclusivity, this goal is not achieved by creating a new IP. Instead, only the marketing of the product is regulated. Seeming wrongly placed at first glance, the chosen legal tool is appropriate at a second glance. Whereas patent law seeks to foster technological creativity in an undirected manner, the orphan drug regulation creates a directed incentive seeking to enhance the development (e. g. by conducting clinical trials) of a specific type of product (orphan drugs).

#### 1.2 Data and Marketing Protection for Pharmaceuticals

Likewise, the eight years’ data protection and ten years’ marketing protection (which may be extended by one additional year for a significant new indication) provided by Directive 2001/83/EC (as amended by Directive 2004/27/EC) and Regulation (EC) No 726/2004 act as an incentive for clinical trials which are nec-

<sup>21</sup> Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products.

<sup>22</sup> Art. 3 (1) Regulation (EC) No 141/2000.

<sup>23</sup> Art. 8 (1) Regulation (EC) No 141/2000.

essary to obtain marketing authorisation.<sup>24</sup> Such trials can be seen as late-stage developmental activities.<sup>25</sup> The economic significance of such developmental activities is increased by the advent of biopharmaceuticals (biologics) which do not only cause higher early-stage research and development costs (development of the substance) but may also lead to higher costs for clinical trials due to their complexity and allergenic potential.<sup>26</sup> Unlike orphan drug exclusivity,<sup>27</sup> the marketing protection provided by Directive 2001/83/EC is no real market exclusivity per se. Generic manufacturers are free to conduct clinical tests on their own and rely on the obtained results for their own application. This is also facilitated by patent law which provides a special exemption for clinical testing.<sup>28</sup> However, due to the increased requirements for clinical tests, quite often generic pharmaceutical manufacturers wishing to conduct clinical trials that are completely similar to those already conducted by original manufacturers will not get the consent of the ethics committees involved due to the unnecessary testing on humans.<sup>29</sup> Moreover, quite often conducting new tests simply will not be economical.

<sup>24</sup> Art. 10 (1) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004); Art. 14 (11) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency. Meier, in: Meier/von Czettritz/Gabriel/Kaufmann, Pharmarecht, 2014, 176 seq., speaks about a reward for conducting [better: sponsoring] clinical trials and publishing the results. According to Fackelmann, in: Drexel/Lee, Pharmaceutical Innovation, competition and patent law, 2013, 141, 178, especially at an early stage of the research and development process, when it is uncertain whether a patentable invention will result, data exclusivity may act as an indirect incentive for innovation. The ECJ describes data exclusivity as an “exclusive right” and a “right to property relating to pharmacological, toxicological and clinical data”, ECJ, Case C-368/96, *The Queen v The Licensing Authority* established by the Medicines Act 1968 (acting by The Medicines Control Agency), ex parte Generics (UK) Ltd and Others, ECR I-7967 (1998), par. 79 et. seq., par. 82 and 83.

<sup>25</sup> The substance is further developed into a marketable product.

<sup>26</sup> Cf. Fuller, Biologicals, Ch. 13, 403, 406 seqq., in: Shorthose (ed.), Guide to EU Pharmaceutical Regulatory Law, 3<sup>rd</sup> ed., 2012. Although biosimilars are not generics of the reference medicinal products whose bioequivalence can be demonstrated, they may also benefit from existing data after the expiry of data and market exclusivity due to art. 10 (4) Directive 2001/83/EC.

<sup>27</sup> Art. 8 (1) Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999.

<sup>28</sup> The so-called Roche-Bolar exemption, Art. 10 (6) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (as amended by Directive 2004/27/EC).

<sup>29</sup> Cf. Art. 4 Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC. The situation is different with biosimilars which are not identical with the reference product and lead to clinical tests not being the same.

### 1.3 Regulatory Law as “another” IP

All in all, regulatory provisions are increasingly used as an incentive for “wanted” technologies. Although arguably public spending or tax exemptions might be a better, more transparent way to selectively push forward specific technologies, regulatory market exclusivity has become a tool of choice maybe due to its cost neutrality for the state. An impressive example from the US is the ultra-long 12 years market exclusivity for an original biopharmaceutical<sup>30</sup> and the extra exclusivity for the first approved interchangeable biosimilar.<sup>31</sup> From a patent lawyer’s perspective, technology-specific regulatory law is indeed better suited as an incentive for downstream development costs (like clinical trials) than patent protection which is not only due to art. 27 (1) TRIPS but also due to the function of incentivising the unknown necessarily technology neutral. However, even this technology neutrality has come under attack recently.

## 2. Patent Law as a Promoter for Specific Technologies?

Patent law shows some tendencies to leave its position as a technology neutral incentive for future innovations.<sup>32</sup> The *ordre public* exception has been expanded especially in Europe being used as a tool against “unwanted” technologies. Likewise, the exception for essentially biological processes has been expanded. Some authors even propose to amend existing patent law in order to create an extra incentive for “useful” technologies like environmentally friendly technologies.

### 2.1 *Ordre Public* Exception and Ethical Considerations

The current trend of charging patent law with ethical considerations was bolstered with the implementation of the Biotechnology Directive.<sup>33</sup> The formerly slim *ordre public* exception (in the European Patent Convention art. 53 (a) EPC) which traditionally is interpreted narrowly and had only been serving as a “bail out” for extreme cases of unethical inventions, was amended by a whole list of life sciences inventions whose use is deemed to be unethical.<sup>34</sup> Furthermore, with its *Brüstle* decision<sup>35</sup> the Court of Justice of the European Union (CJEU) expanded this exemption even more. The unpatentability of embryonic stem

<sup>30</sup> 42 U.S.C. 262(k)(7)(A).

<sup>31</sup> 42 U.S.C. 262(k)(6).

<sup>32</sup> For US patent law see *Burk/Lemley*, Is Patent Law Technology Specific?, Berkeley Tech. L. J. 17 (2002), 1157, 1158: “As a practical matter, it appears, while patent law is technology-neutral in theory, it is technology-specific in application.”

<sup>33</sup> It arguably started even earlier, e.g. with EPO’s Harvard Oncomouse decision, T 19/90 (OJ 1990,476) – *Transgenic Mouse/HARVARD*.

<sup>34</sup> Art. 6 (2) EC Directive 98/44.

<sup>35</sup> ECJ, Case C-34/10, *Oliver Brüstle v Greenpeace e.V.*

cells, a technology which is legal under regulatory law in many member states, turns the relation between patent law and regulatory law upside down. Besides, by taking into account how an invention was made the CJEU arguably did away with a fundamental principle in the interpretation of the *ordre public* exemption, stating that unethical or illegal behaviour in the process of creating an invention (the “stolen microscope”) does not influence the patentability of an invention. In effect, patent law has become the leading force in suppressing stem cell technology as a politically unwanted technology. This may change when stem cell technology leaves its current state as an emerging technology and yields first results in human medicine.

## 2.2 Exception for Essentially Biological Processes

Another boundary where ethical and technological neutrality of patent law currently is at stake is the exception for essentially biological processes (article 53 (b) EPC) concerning plant breeding methods. The EPO Enlarged Board of Appeal Broccoli II/Tomatoes II case is still underway.<sup>36</sup> Although it seems consequent to apply the patentability exception to the products of smart breeding methods when the methods themselves are exempt (teleological interpretation certainly allows for an application beyond the scope of the mere wording), the wisdom of the Enlarged Board of Appeals’ first decision (Broccoli I/Tomatoes I)<sup>37</sup> pulling smart breeding methods under the exemption may be doubted. If, in effect, after the pending second decision the majority of current developmental activities in crop science are no longer protectable by patent law and plant variety protection alike, this would clearly be detrimental to innovative activity in the whole sector. However, maybe regulatory seed law might be a solution to this problem.

## 2.3 Privileging Specific Technologies?

Last but not least, patent law is not only used to discourage “unwanted” technologies but according to some proposals<sup>38</sup> shall also be used to encourage specifically certain “wanted” technologies. The main argument against such amendments to patent law is the competence argument. Patent offices are competent to judge the novelty and the amount of creativity (inventiveness) of an invention. They are not suitable to judge a future usefulness (which market success will show) or ethical implications of the invention which have to be decided by political channels, especially legislation laying down regulatory rules, and subsequently by ethics committees. Furthermore, technology neutrality is one of the cornerstones

<sup>36</sup> Referrals pending before the Enlarged Board of Appeal, Cases G 2/13 and 2/12.

<sup>37</sup> Cases G 2/07 – *Broccoli/PLANT BIOSCIENCE*, G 1/08 – *Tomatoes/STATE OF ISRAEL*.

<sup>38</sup> *Derclaye*, Intellectual Property Rights and Global Warming, *Marquette Intellectual Property Law Review* 12 (2008), 263, 286 seqq.

of patent law. Both criteria, novelty and inventiveness, are open to any sector of technology including fundamentally new ones hitherto unknown. By fostering the development of new technologies without categorising and judging it by economic, ecological, ethical or any other non-technological standard patent law increases the overall amount of new technologies. The further assessment of these technologies has to be carried out from an *ex post* perspective. Patent law necessarily takes an *ex ante* perspective.

## VI. Conclusions

IP protection is one of the main pillars of technology law. In the area of life sciences, IP law faces some challenges which are connected with the distribution of functions between IP law and regulatory law. Incentivising specific technology by granting market exclusivity under regulatory law faces some doubts but nevertheless regulatory law is better suited to provide for such technology-specific rules than patent law. From an economic perspective, creating special incentives for downstream developmental innovations can be considered a positive approach. Nevertheless, patent law should remain technology neutral and refrain from ethical or usefulness considerations as much as possible. Life sciences, being highly innovative, capital intensive and often charged with ethical implications, are not only driven by law, but also drive legal development. The role of IP law in the life sciences area remains a field of many interesting questions of legal research.

## Zusammenfassung

Die Life Sciences und ihre industrielle Anwendung haben sich zu einem der führenden Technikbereiche entwickelt. Dieser Technikbereich weist eine hohe Innovationsrate und einen großen Investitionsbedarf auf, weshalb er auf geistiges Eigentum besonders angewiesen ist. Das Recht des geistigen Eigentums entfaltet dabei seine Regelungswirkung im Zusammenspiel mit anderen Rechtsgebieten, insbesondere mit dem regulatorischen Recht (Sicherheitsrecht) und dem Haftungsrecht. Im Life Sciences-Bereich ist es in besonderem Maße erforderlich, dass das Recht nicht nur Innovationsanreize setzt und Technologietransfer ermöglicht, sondern auch die Sicherheit bei der Technikanwendung gewährleistet und verbleibende Risiken verteilt. Die traditionelle Aufgabenverteilung zwischen den einzelnen Rechtsgebieten wird dabei jedoch zunehmend verwischt: Zulassungsrecht als klassisches Sicherheitsrecht dient auch der Schaffung von Anreizen für Entwicklungsaktivitäten wie klinische Studien während das Patentrecht zunehmend auch dazu herangezogen wird, von unerwünschten Aktivitäten abzuschrecken.

Der Beitrag versucht zu zeigen, inwiefern geistiges Eigentum als Teil des Technikrechts begriffen werden kann und wie die Life Sciences einen derjenigen Technikbereiche darstellen, der für das rechtliche Eingreifen in Technikentwicklung und -anwendung neue

Herausforderungen bereithält. Life Sciences werden dabei als Einsatz und Behandlung von Lebewesen verstanden, wobei der Begriff „Sciences“ entgegen dem ursprünglichen Wort-sinn eher als Anwendung von Wissenschaft (Technologie) zu verstehen ist, der Einsatz von Lebewesen als Biotechnologie und die Behandlung von Lebewesen als Zusammenfassung von Medizin, Tiermedizin und Pflanzenschutz. Damit sind wirtschaftlich insbesondere die Bereiche Medizin, Pharma und Pflanzen umfasst. Technikrecht wird als techniksteuerndes Recht verstanden, das zugleich auf technische Innovationen reagieren muss. Es weist vier grundlegende Regelungszwecke auf: Innovationsförderung (geistiges Eigentum), Technologietransfer (Vertragsrecht), Risikominimierung (Sicherheitsrecht) und Risikoverteilung (Haftungsrecht). Eine besondere Forschungsaufgabe des Technikrechts ist es dabei, gerade die Querbezüge zwischen diesen einzelnen Bereichen zu untersuchen.